



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0007]

Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2017

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for fiscal year (FY) 2017 generic new animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Animal Generic Drug User Fee Amendments of 2013 (AGDUFA II), authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, and for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. This notice establishes the fee rates for FY 2017.

FOR FURTHER INFORMATION CONTACT: Visit FDA's Web site at

<http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm>

m, or contact Lisa Kable, Center for Veterinary Medicine (HFV-10), Food and Drug

Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6888. For general questions,

you may also email the Center for Veterinary Medicine (CVM) at cvmagdufa@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 741 of the FD&C Act (21 U.S.C. 379j-21) establishes three different types of user fees: (1) Fees for certain types of abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j-21(a)). When certain conditions are met, FDA will waive or reduce fees for generic new animal drugs intended solely to provide for a minor use or minor species indication (21 U.S.C. 379j-21(d)).

For FY 2014 through FY 2018, the FD&C Act establishes aggregate yearly base revenue amounts for each of these fee categories (21 U.S.C. 379j-21(b)). Base revenue amounts established for fiscal years after FY 2014 are subject to adjustment for workload (21 U.S.C. 379j-21(c)). The target revenue amounts for each fee category for FY 2017, after the adjustment for workload, are as follows: For application fees the target revenue amount is \$2,835,000; for product fees the target revenue amount is \$4,253,000; and for sponsor fees the target revenue amount is \$4,253,000.

For FY 2017, the generic new animal drug user fee rates are: \$232,400 for each abbreviated application for a generic new animal drug other than those subject to the criteria in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); \$116,200 for each abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4); \$10,200 for each generic new animal drug product; \$96,350 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; \$72,263 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and \$48,175 for each generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for FY 2017 product and sponsor fees by December 31, 2016. These fees will be due by January 31, 2017. The application fee rates are

effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2016, and will remain in effect through September 30, 2017. Applications will not be accepted for review until FDA has received full payment of related application fees and any other fees owed under the Animal Generic Drug User Fee program (AGDUFA program).

II. Revenue Amount for FY 2017

A. Statutory Fee Revenue Amounts

AGDUFA II, Title II of Pub. L. 113-14, specifies that the aggregate revenue amount for FY 2017 for abbreviated application fees is \$1,984,000 and each of the other two generic new animal drug user fee categories, annual product fees and annual sponsor fees, is \$2,976,000 each (see 21 U.S.C. 379j-21(b)).

B. Inflation Adjustment to Fee Revenue Amount

The amounts established in AGDUFA II for each year for FY 2014 through FY 2018 include an inflation adjustment; therefore, no further inflation adjustment is required.

C. Workload Adjustment Fee Revenue Amount

For each FY beginning after FY 2014, AGDUFA II provides that statutory fee revenue amounts shall be further adjusted to reflect changes in review workload. (See 21 U.S.C. 379j-21(c)(2).)

FDA calculated the average number of each of the four types of applications and submissions specified in the workload adjustment provision (abbreviated applications for generic new animal drugs, manufacturing supplemental abbreviated applications for generic new animal drugs, investigational generic new animal drug study submissions, and investigational generic new animal drug protocol submissions) received over the 5-year period that ended on September

30, 2013 (the base years), and the average number of each of these types of applications and submissions over the most recent 5-year period that ended on June 30, 2016.

The results of these calculations are presented in the first two columns in table 1. Column 3 reflects the percent change in workload over the two 5-year periods. Column 4 shows the weighting factor for each type of application, reflecting how much of the total FDA generic new animal drug review workload was accounted for by each type of application or submission in the table during the most recent 5 years. Column 5 is the weighted percent change in each category of workload and was derived by multiplying the weighting factor in each line in column 4 by the percent change from the base years in column 3. At the bottom right of table 1, the sum of the values in column 5 is calculated, reflecting a total change in workload of 42.9097 percent for FY 2017. This is the workload adjuster for FY 2017.

Table 1.--Workload Adjuster Calculation

Application Type	Column 1 5-Year Average (Base Years)	Column 2 Latest 5- Year Average	Column 3 Percent Change	Column 4 Weighting Factor	Column 5 Weighted Percent Change
Abbreviated New Animal Drug Applications (ANADAs)	25.0	29.8	19.2000	0.3730	7.1620
Manufacturing Supplements ANADAs	128.0	145.2	13.4375	0.2667	3.5837
Generic Investigational Study Submissions	23.0	48.0	108.6957	0.2411	26.2031
Generic Investigational Protocol Submissions	17.2	25.8	50.0000	0.1192	5.9609
FY 2017 AGDUFA II Workload Adjuster					42.9097

Over the last year FDA has continued to see more sponsors getting involved in the generic animal drug approval process, including pioneer sponsors. This has contributed to sustained increases in the number of ANADAs, manufacturing supplements, and protocols submitted. Additionally, more sponsors continue to pursue drug approvals that do not qualify for a waiver of the requirement to conduct an in vivo bioequivalence study. For this reason we are

seeing a large sustained increase in the number of generic investigational new animal drug study submissions.

As a result, the statutory revenue amount for each category of fees for FY 2017 (\$1,984,000 for application fees and \$2,976,000 for both product and sponsor fees) must now be increased by 42.9097 percent, for a total fee revenue target in FY 2017 of \$11,341,000 (rounded to the nearest thousand dollars) for fees from all three categories. The target for application fee revenue is \$1,984,000 times 42.9097 percent, for a total of \$2,835,000, rounded to the nearest thousand. The target for product fee revenue is \$2,976,000 times 42.9097 percent, for a total of \$4,253,000, rounded to the nearest thousand dollars, and the target for sponsor fee revenue is the same as for product fees (\$4,253,000, rounded to the nearest thousand dollars).

III. Abbreviated Application Fee Calculations for FY 2017

A. Application Fee Revenues and Numbers of Fee-Paying Applications

Each person that submits an abbreviated application or a supplemental abbreviated application for a generic new animal drug shall be subject to an application fee, with limited exceptions (21 U.S.C. 379j-21(a)(1)). The term “abbreviated application for a generic new animal drug” means an abbreviated application for the approval of any generic new animal drug submitted under section 512(b)(2) (21 U.S.C. 379j-21(k)(1)). A “supplemental abbreviated application for a generic new animal drug” is defined as a request to the Secretary to approve a change in an approved abbreviated application (21 U.S.C. 379j-21(k)(11)). The application fees are to be set so that they will generate \$2,835,000 in fee revenue for FY 2017.

To set fees for abbreviated applications for generic new animal drugs to realize \$2,835,000, FDA must first make some assumptions about the number of fee-paying abbreviated applications it will receive during FY 2017.

The Agency knows the number of applications that have been submitted in previous years. That number fluctuates from year to year. FDA is making estimates and applying different assumptions for two types of full fee submissions: Original submissions of abbreviated applications for generic new animal drugs and "reactivated" submissions of abbreviated applications for generic new animal drugs. Any original submissions of abbreviated applications for generic new animal drugs that were received by FDA before July 1, 2008, were not assessed fees (21 U.S.C. 379j-21(a)(1)(A)). Some of these non-fee-paying submissions were later resubmitted on or after July 1 because the initial submission was not approved by FDA (i.e., FDA marked the submission as incomplete and requested additional non-administrative information) or because the original submission was withdrawn by the sponsor. Abbreviated applications for generic new animal drugs resubmitted on or after July 1, 2008, are subject to user fees. In this notice, FDA refers to these resubmitted applications as "reactivated" applications.

Also, under AGDUFA II, an abbreviated application for an animal generic drug subject to the criteria in section 512(d)(4) of the FD&C Act and submitted on or after October 1, 2013, shall be subject to 50 percent of the fee applicable to all other abbreviated applications for a generic new animal drug (21 U.S.C. 379j-21(a)(1)(C)(ii)).

Regarding original submissions of abbreviated applications for generic new animal drugs, FDA is assuming that the number of applications that will pay fees in FY 2017 will equal the average number of submissions over the 5 most recently completed years of the AGDUFA program (FY 2011-FY 2015). FDA believes that this is a reasonable approach after 7 complete years of experience with this program.

The average number of original submissions of abbreviated applications for generic new animal drugs over the 5 most recently completed years is 10 applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 4.4 submissions subject to the criteria in section 512(d)(4). Each of the submissions described under section 512(d)(4) of the FD&C Act pays 50 percent of the fee paid by the other applications and will be counted as one half of a fee. Adding all of the applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 50 percent of the number that are subject to such criteria results in a total of 12.2 anticipated full fees.

In prior years, FDA had estimated the number of reactivations of abbreviated applications for generic new animal drugs that had been originally submitted prior to July 1, 2008. Over the years, that number has decreased to the point that FDA no longer expects to receive any reactivations of applications initially submitted prior to July 1, 2008, and will include no provision for them in its fee estimates. Should such a submission be made, the submitter will be expected to pay the appropriate fee.

Based on the previous assumptions, FDA is estimating that it will receive a total of 12.2 fee-paying generic new animal drug applications in FY 2017 (10 original applications paying a full fee and 4.4 applications paying a half fee).

B. Application Fee Rates for FY 2017

FDA must set the fee rates for FY 2017 so that the estimated 12.2 abbreviated applications that pay the fee will generate a total of \$2,835,000. To generate this amount, the fee for a generic new animal drug application, rounded to the nearest hundred dollars, will have to be \$232,400, and for those applications that are subject to the criteria set forth in section 512(d)(4) of the FD&C Act, 50 percent of that amount, or \$116,200.

IV. Generic New Animal Drug Product Fee Calculations for FY 2017

A. Product Fee Revenues and Numbers of Fee-Paying Products

The generic new animal drug product fee (also referred to as the product fee) must be paid annually by the person named as the applicant in an abbreviated application or supplemental abbreviated application for a generic new animal drug product submitted for listing under section 510 of the FD&C Act (21 U.S.C. 360), and who had an abbreviated application or supplemental abbreviated application for a generic new animal drug product pending at FDA after September 1, 2008 (see 21 U.S.C. 379j-21(a)(2)). The term "generic new animal drug product" means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug has been approved (21 U.S.C. 379j-21(k)(6)). The product fees are to be set so that they will generate \$4,253,000 in fee revenue for FY 2017.

To set generic new animal drug product fees to realize \$4,253,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2017. FDA gathered data on all generic new animal drug products that have been submitted for listing under section 510 of the FD&C Act and matched this to the list of all persons who FDA estimated would have an abbreviated new animal drug application or supplemental abbreviated application pending after September 1, 2008. As of June 2016, FDA estimates a total of 417 products submitted for listing by persons who had an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug pending after

September 1, 2008. Based on this, FDA believes that a total of 417 products will be subject to this fee in FY 2017.

In estimating the fee revenue to be generated by generic new animal drug product fees in FY 2017, FDA is assuming that less than two products invoiced will qualify for minor use/minor species fee waiver (see 21 U.S.C. 379j-21(d)). FDA has kept this estimate at zero percent this year, based on historical data over the past 5 completed years of the AGDUFA program.

Accordingly, the Agency estimates that a total of 417 products will be subject to product fees in FY 2017.

B. Product Fee Rates for FY 2017

FDA must set the fee rates for FY 2017 so that the estimated 417 products that pay fees will generate a total of \$4,253,000. To generate this amount will require the fee for a generic new animal drug product, rounded to the nearest \$5, to be \$10,200.

V. Generic New Animal Drug Sponsor Fee Calculations for FY 2017

A. Sponsor Fee Revenues and Numbers of Fee-Paying Sponsors

The generic new animal drug sponsor fee (also referred to as the sponsor fee) must be paid annually by each person who: (1) Is named as the applicant in an abbreviated application for a generic new animal drug, except for an approved application for which all subject products have been removed from listing under section 510 of the FD&C Act, or has submitted an investigational submission for a generic new animal drug that has not been terminated or otherwise rendered inactive and (2) had an abbreviated application for a generic new animal drug, supplemental abbreviated application for a generic new animal drug, or investigational submission for a generic new animal drug pending at FDA after September 1, 2008 (see 21 U.S.C. 379j-21(k)(7) and 379j-21(a)(3), respectively). A generic new animal drug sponsor is

subject to only one such fee each fiscal year (see 21 U.S.C. 379j-21(a)(3)(C)). Applicants with more than six approved abbreviated applications will pay 100 percent of the sponsor fee; applicants with more than one and fewer than seven approved abbreviated applications will pay 75 percent of the sponsor fee; and applicants with one or fewer approved abbreviated applications will pay 50 percent of the sponsor fee (see 21 U.S.C. 379j-21(a)(3)(C)). The sponsor fees are to be set so that they will generate \$4,253,000 in fee revenue for FY 2017.

To set generic new animal drug sponsor fees to realize \$4,253,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2017. FDA now has 7 complete years of experience collecting these sponsor fees. Based on the number of firms that meet this definition and the average number of firms paying fees at each level over the 5 most recently completed years of the AGDUFA program (FY 2011 through FY 2015), FDA estimates that in FY 2017, 13 sponsors will pay 100 percent fees, 18 sponsors will pay 75 percent fees, and 38 sponsors will pay 50 percent fees. That totals the equivalent of 45.5 full sponsor fees (13 times 100 percent or 13, plus 18 times 75 percent or 13.5, plus 38 times 50 percent or 19).

FDA estimates that about 3 percent of all of these sponsors, or 1.37, may qualify for a minor use/minor species fee waiver (see 21 U.S.C. 379j-21(d)). FDA has reduced the estimate of the percentage of sponsors that will not pay fees from 4 percent to 3 percent this year, based on historical data over the past 5 completed years of the AGDUFA program.

Accordingly, the Agency estimates that the equivalent of 44.13 full sponsor fees (45.5 minus 1.37) are likely to be paid in FY 2017.

B. Sponsor Fee Rates for FY 2017

FDA must set the fee rates for FY 2017 so that the estimated equivalent of 44.13 full sponsor fees will generate a total of \$4,253,000. To generate this amount will require the 100 percent fee for a generic new animal drug sponsor, rounded to the nearest \$50, to be \$96,350. Accordingly, the fee for those paying 75 percent of the full sponsor fee will be \$72,263, and the fee for those paying 50 percent of the full sponsor fee will be \$48,175.

VI. Fee Schedule for FY 2017

The fee rates for FY 2017 are summarized in table 2 of this document.

Table 2.--FY 2017 Fee Rates

Generic New Animal Drug User Fee Category	Fee Rate for FY 2017
Abbreviated Application Fee for Generic New Animal Drug except those subject to the criteria in section 512(d)(4)	\$232,400
Abbreviated Application Fee for Generic New Animal Drug subject to the criteria in section 512(d)(4)	116,200
Generic New Animal Drug Product Fee	10,200
100 Percent Generic New Animal Drug Sponsor Fee ¹	96,350
75 Percent Generic New Animal Drug Sponsor Fee ¹	72,263
50 Percent Generic New Animal Drug Sponsor Fee ¹	48,175

¹ An animal drug sponsor is subject to only one fee each fiscal year.

VII. Procedures for Paying FY 2017 Generic New Animal Drug User Fees

A. Abbreviated Application Fees and Payment Instructions

The FY 2017 fee established in the new fee schedule must be paid for an abbreviated new animal drug application subject to fees under AGDUFA II that is submitted on or after October 1, 2016. Payment must be made in U.S. currency from a U.S. bank by check, bank draft, U.S. postal money order payable to the order of the Food and Drug Administration, wire transfer, or electronically using Pay.gov. The preferred payment method is online using electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay> or the Pay.gov payment option is available to you after you submit a cover sheet. Once you search for your invoice, click “Pay Now” to be

redirected to Pay.gov. Note that electronic payment options are based on the balance due. Payment by credit card is available for balances less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be drawn on U.S bank accounts as well as U.S. credit cards.

On your check, bank draft, U.S. or postal money order, please write your application's unique Payment Identification Number, beginning with the letters "AG", from the upper right-hand corner of your completed Animal Generic Drug User Fee Cover Sheet. Also write the FDA post office box number (P.O. Box 979033) on the enclosed check, bank draft, or money order. Your payment and a copy of the completed Animal Generic Drug User Fee Cover Sheet can be mailed to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197-9000.

If payment is made via wire transfer, send payment to U. S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account No.: 75060099, Routing No.: 021030004, Swift No.: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993-0002. You are responsible for any administrative costs associated with the processing of a wire transfer. Contact your bank or financial institution about the fee and add it to your payment to ensure that your fee is fully paid.

If you prefer to send a check by a courier, the courier may deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery contact the U.S. Bank at 314-418-4013. This phone number is only for questions about courier delivery.)

The tax identification number of FDA is 53-0196965. (Note: In no case should the payment for the fee be submitted to FDA with the application.)

It is helpful if the fee arrives at the bank at least a day or two before the abbreviated application arrives at FDA's Center for Veterinary Medicine (CVM). FDA records the official abbreviated application receipt date as the later of the following: The date the application was received by CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U. S. Department of the Treasury notifies FDA of payment. U.S. Bank and the United States Treasury are required to notify FDA within 1 working day, using the Payment Identification Number described previously.

B. Application Cover Sheet Procedures

Step One--Create a user account and password. Log onto the AGDUFA Web site at <http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm137049.htm> and scroll down the page until you find the link "Create AGDUFA User Fee Cover Sheet." Click on that link and follow the directions. For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two--Create an Animal Generic Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Generic Drug User Fee Cover Sheet. One cover sheet is needed for each abbreviated animal drug application. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it

electronically to FDA and you will be able to print a copy of your cover sheet showing your unique Payment Identification Number.

Step Three--Send the payment for your application as described in Section VII.A of this document.

Step Four--Please submit your application and a copy of the completed Animal Generic Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV-199), 7500 Standish Pl., Rockville, MD 20855.

C. Product and Sponsor Fees

By December 31, 2016, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2017 using this fee schedule. Fees will be due by January 31, 2017. FDA will issue invoices in November 2017 for any products and sponsors subject to fees for FY 2017 that qualify for fees after the December 2016 billing.

Dated: July 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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